



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 12 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

William J. Kennick, Esq.  
1755 York Avenue  
New York, NY 10128

**Re: Citizen Petition – Docket Number FDA-2008-P-0197**

Dated: March 14, 2008

Received: March 26, 2008

Dear Mr. Kennick:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition filed on March 26, 2008. Your petition requests that the agency determine whether the Tomatis Electronic Ear is a medical device.

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact Deborah Wolf of our Regulation Staff at (240) 276-2348.

Sincerely,

A handwritten signature in black ink, appearing to read "Catherine M. Cook", is written over a horizontal line.

Catherine M. Cook  
Acting Associate Director  
for Regulation and Policy  
Center for Devices and  
Radiological Health